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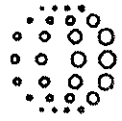

MAR 15 2012

510(K) Summary

In accordance with the Food and Drug Admisnistration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the device.

Submitted By:	Berkeley Advanced Biomaterials, Inc.
Date:	20 December 2011
Contact Person:	François Génin, Ph.D.
Position:	Chief Executive Officer
Contact Information:	Phone: 510-883-0500; Fax: 510-883-0511
Proprietary Name:	B-GENIN, R-GENIN
Regulation Name:	Resorbable Calcium Salt Bone Void Filler
Regulation Number:	888.3045
Classification:	Class II
Device Code/ Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USE

B-GENIN and R-GENIN are indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. The product should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, posterolateral spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. The bone graft can be mixed with autogenous blood prior to use at the physician's discretion.

B. DEVICE DESCRIPTION

B-GENIN is a bone void filler consisting of resorbable purified fibrillar bovine collagen and demineralized bone matrix (DBM). The device is an implant where new bone can grow.
R-GENIN is a bone void filler consisting of resorbable purified fibrillar bovine collagen, hydroxyapatite, tri-calcium phosphate, and DBM. The device is an implant where new bone can grow.

C. VIRAL INACTIVATION

The processing methods were evaluated for their viral inactivation potential. A select panel of viruses representing various virus types, shapes and genomes were evaluated. The panel included human immunodeficiency virus (HIV-1), hepatitis A virus, hepatitis C virus (bovine viral diarrhea as model), porcine parvovirus, and pseudorabies virus. The tests demonstrated suitable viral inactivation potential of the processing methods. The product is also terminally sterilized by gamma sterilization to also ensure its biological sterility.

D. OSTEOCONDUCTIVE POTENTIAL:

Each batch of DBM used in production is tested for osteoinductive potential using an athymic nude-

mouse model. The test involves an evaluation for histopathological evidence of new bone formation after intramuscular implantation of the test article. The product and process consistency is confirmed with this athymic nude-mouse model that utilizes a five-point linear scale (0,1,2,3,4) to score bone formation at 28 days*. The osteoinduction assay results using this assay should not be interpreted to predict clinical performance in human subject.

* Edwards, J. T., Diegmann M. N., Scarborough, N. L.: Osteoinduction of human demineralized bone: characterization in a rat model, *Clin. Orthopaedics*, Vol. 357, pp. 219-28 (1998).

E. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, materials and design features of the devices described above are substantially equivalent to B-GENIN and R-GENIN (K091912) previously cleared for market. The safety and effectiveness of the devices are adequately supported by the substantial equivalence information provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Berkeley Advanced Biomaterials, Incorporated
% François Génin, Ph.D.
Chief Executive Officer
901 Grayson Street, Suite 101
Berkeley, California 94710

MAR 15 2012

Re: K113791
Trade/Device Name: B-GENIN, R-GENIN
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: December 20, 2011
Received: December 22, 2011

Dear Dr. Génin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Deputy Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K113791

Device Name: **B-GENIN, R-GENIN**

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113791